

cont B1

(b) detecting the presence of said target polynucleotide in the test sample.

B2

3. (Twice Amended) A method for detecting mRNA of a target lipocalin-encoding polynucleotide indicative of breast [tissue disease] cancer in a test sample, comprising:

(a) performing reverse transcription with at least one primer in order to produce cDNA;

(b) amplifying the cDNA obtained from step to obtain an amplicon, said amplifying using sense and antisense primers wherein each primer comprises at least about 10 nucleotides having at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2; position 1-357 of SEQUENCE ID NO 4; position 1-357 of SEQUENCE ID NO 5; and complements thereof; and

(c) detecting the presence of amplicon, wherein the presence of the amplicon indicates detection of the target polynucleotide indicative of breast [tissue disease] cancer in the test sample.

B3

6. (Twice Amended) A method of detecting a target lipocalin-encoding polynucleotide indicative of breast [tissue disease] cancer in a test sample suspected of containing said target, comprising:

(a) contacting said test sample with at least one sense primer and with at least anti-sense primer wherein each primer comprises at least about 10 nucleotides having at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO: 1, SEQUENCE ID NO 2, position 1-357 of SEQUENCE ID NO 4, position 1-357 of SEQUENCE ID NO 5 and complements thereof and amplifying to obtain a first stage reaction product;

(b) contacting said first stage reaction product with at least one oligonucleotide probe to obtain a second stage reaction product, with the proviso that the oligonucleotide probe is (i) located 3' to the sense and antisense primers utilized in step (a) and (ii) is complementary to said first stage reaction product, wherein the probe comprises at least about 10 contiguous nucleotides having at least 90% identity with a

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B3
polynucleotide selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, position 1-357 of SEQUENCE ID NO 4, position 1-357 of SEQUENCE ID NO 5 and complements thereof; and

(c) detecting said second stage reaction product as an indication of the presence of the target polynucleotide indicative of breast [tissue disease]cancer in the test sample.

B4
10. (Twice Amended) A test kit useful for detecting a target lipocalin-encoding polynucleotide indicative of breast tissue disease in a test sample, comprising a container containing at least one polynucleotide selected from the group consisting of a polynucleotide having at least [50%] 90% identity over the entire length of [with] SEQUENCE ID NO 1, SEQUENCE ID NO 2, [or complements thereof; and a polynucleotide having at least 60% identity with] position 1-357 of SEQUENCE ID NO 4, position 1-357 of SEQUENCE ID NO 5 or complements thereof.

11. (Twice Amended) A purified lipocalin-encoding polynucleotide selected from the group consisting of a polynucleotide having at least [50%] 90% identity over the entire length of [with] SEQUENCE ID NO 1, SEQUENCE ID NO 2, [or complements thereof; and a polynucleotide having at least 60% identity with] position 1-357 of SEQUENCE ID NO 4, position 1-357 of SEQUENCE ID NO 5 or complements thereof.

B5
15. (Twice Amended) A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host, wherein said open reading frame is selected from the group consisting of a lipocalin-encoding polynucleotide having at least [50%] 90% identity over the entire length of [with] SEQUENCE ID NO 1, SEQUENCE ID NO 2, [or complements thereof; and a polynucleotide having at least 60% identity with] position 1-357 of SEQUENCE ID NO 4, position 1-357 of SEQUENCE ID NO 5, or complements thereof.

B6
30. (Twice Amended) A cell transfected with a nucleic acid sequence encoding at least one epitope, wherein said nucleic acid sequence is selected from the group consisting of a lipocalin-encoding polynucleotide having at least [50%] 90% identity over the entire length of [with] SEQUENCE ID NO 1, SEQUENCE ID NO 2 [or complements thereof; and a polynucleotide having at least 60% identity with] position 1-

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357 of SEQUENCE ID NO 4, position 1-357 of SEQUENCE ID NO 5 or complements thereof.

B7
33. (Twice Amended) A composition of matter comprising a lipocalin-encoding polynucleotide selected from the group consisting of: (a) a polynucleotide having at least [50%] 90% identity over the entire length of [to] SEQUENCE ID NO 1, SEQUENCE ID NO 2 [and complements thereof, and (b) least 60% identity to] position 1-357 of SEQUENCE ID NO 4, position 1-357 of SEQUENCE ID NO 5 and complements thereof.

B7
38. (Twice Amended) A purified lipocalin-encoding polynucleotide which codes for a protein which comprises an amino acid sequence having at least [50%] 90% identity with SEQUENCE ID NO 22.

39. (Twice Amended) A purified lipocalin-encoding polynucleotide comprising DNA having at least [60%] 90% identity over the entire length of [with] position 1-357 of SEQUENCE ID NO 4 or position 1-357 of SEQUENCE ID NO 5.

40. (Twice Amended) The method of claim 1 wherein the presence of said target polynucleotide in said test sample is indicative of breast [disease] cancer.

Please add the following claims:

B9
45. (new) (Twice Amended) A purified lipocalin-encoding polynucleotide comprising DNA having at least 90% identity over the entire length of SEQUENCE ID NO 4 or SEQUENCE ID NO 5.

46. (new) A method of detecting the presence of a target lipocalin-encoding polynucleotide in a test sample, comprising:

(a) contacting said test sample with at least one diagnostic polynucleotide selected from the group consisting of a polynucleotide having at least 90% identity over the entire length of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 4, SEQUENCE ID NO 5 or complements thereof; and

(b) detecting the presence of said target polynucleotide in said test sample.

47. (new) A method for detecting mRNA of a target lipocalin-encoding polynucleotide indicative of breast cancer in a test sample, comprising:

- (a) performing reverse transcription with at least one primer in order to produce cDNA;
- (b) amplifying the cDNA obtained from step (a) to obtain an amplicon, said amplifying using sense and antisense primers wherein each primer comprises at least about 10 nucleotides having at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2, SEQUENCE ID NO 4; SEQUENCE ID NO 5; and complements thereof; and
- (c) detecting the presence of amplicon, wherein the presence of the amplicon indicates detection of the target polynucleotide indicative of breast cancer in said test sample.

48. (new) A method of detecting a target lipocalin-encoding polynucleotide indicative of breast cancer in a test sample suspected of containing said target, comprising:

- (a) contacting said test sample with at least one sense primer and with at least anti-sense primer wherein each primer comprises at least about 10 nucleotides having at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO: 1, SEQUENCE ID NO 2, SEQUENCE ID NO 4, SEQUENCE ID NO 5 and complements thereof and amplifying to obtain a first stage reaction product;
- (b) contacting said first stage reaction product with at least one oligonucleotide probe to obtain a second stage reaction product, with the proviso that the oligonucleotide probe is (i) located 3' to the sense and antisense primers utilized in step (a) and (ii) is complementary to said first stage reaction product, wherein the probe comprises at least about 10 contiguous nucleotides having at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 4, SEQUENCE ID NO 5 and complements thereof; and
- (c) detecting said second stage reaction product as an indication of the presence of the target polynucleotide indicative of breast cancer in the test sample.